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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,106	06/02/2000	David A. Wright	P-1065	6179

26191 7590 05/07/2003

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/07/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/586,106

Applicant(s)

WRIGHT ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 9-12, 15-18, 21-23 and 25-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-3, 4, 9-12, 15-18, 21-23 and 25-33 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 are pending in the present rejection. This Office Action is in response to Paper No. 9, filed 11 July 2002.

#### ***Response to Amendment***

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 stand rejected under the written description requirement of 35 U.S.C. 112, first paragraph for the reasons set forth in the Office Action mailed 8 April 2002.

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the Office action mailed 8 April 2002.

The rejection of claims 1-4, 9-12, 15-18, 21-23 and 25-33 under 35 U.S.C. 112, second paragraph have been withdrawn in view of Applicant's Amendment filed 11 July 2002.

#### ***New Grounds of Rejection Necessitated by Applicant's Amendment***

##### ***Claim Rejections - 35 USC § 112 – New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the present claims to remove all reference to the reverse transcriptase encoded by SEQ ID NOs:62 or 63. By doing so Applicant indicating that such activity is not required. Such implication is punctuated by Applicant's arguments on page 8 of the response filed 11 July 2002 which states that "the claimed nucleic acids need not result in a functional reverse transcriptase." This position and amendment is not supported in the specification. Indeed, the specification discloses that the sequences encode at least a portion of a reverse transcriptase as a part of the claimed plant retroelement. For example, the disclosure on page 46, lines 12-20, indicate that reverse transcriptase function is required to facilitate expression of the retroelement. The examiner has not found any mention or implication in the specification that the portions of the reverse transcriptase of SEQ ID Nos:62 or 63 are non-functional.

#### ***Response to Arguments***

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 stand rejected under the written description requirement of 35 U.S.C. 112, first paragraph for the reasons set forth in the Office Action mailed 8 April 2002.

Applicant has amended the claims to remove any reference to the reverse transcriptase encoded by SEQ ID NO:62 or 63. Furthermore, Applicant argues that the sequences with 85% or 95% identity to SEQ ID NO:62 or 63 need not encode a functional reverse transcriptase and thus, the rejection is moot in view of Applicant's amendment.

Applicant should note that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). In the instant case, Applicant argues that the a functional reverse transcriptase is not required and thus the claims are described for any sequence having 85% or 95% identity to SEQ ID NO:62 or 63. Applicant's arguments are noted, however, not found persuasive. Although it may be true that one of skill in the art can using a computer algorithm find all sequences having the requisite identity to SEQ ID NO:62 or 63, the disclosure of the specification does not indicate anywhere that such reverse transcriptase does not function. As cited above, page 46 of the specification indicates that a functional reverse transcriptase is used. Page 56 of the specification teaches that it is desirable to express the claimed retroelement in the plant cell. A functional reverse transcriptase is required in order to do so. Thus, the Applicant still has failed to describe the claimed invention in such a way that one of skill in the art would reasonably conclude that Applicant was in possession of the invention claimed.

Claims 1-4, 9-12, 15-18, 21-23 and 25-33 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the Office action mailed 8 April 2002.

Applicant argues that the sequences encoding the reverse transcriptase with 85% or 95% identity to SEQ ID NOs:62 or 63 need not encode a functional reverse transcriptase. On page 8

of the specification, Applicant specifically states, "the claimed nucleic acids need not result in a functional reverse transcriptase." This assertion begs the question as to whether Applicant's entire plant retroelement is enabled and can be used by one of skill in the art. If there were not a functional reverse transcriptase encoded by the sequence, then it appears that the retroelement construct would not even work in a plant cell transformed with it. Since Applicant's specification indicates that the retroelement is expressed in the plant cell (specifically page 56 and throughout the specification) and that such expression is achieved by a reverse transcriptase (page 46), one of skill in the art would not be able to make and use the invention claimed unless Applicant taught which sequences, allelic variants, and complementary sequences having 85% or 95% identity to SEQ ID Nos: 62 and 63 encoded functional reverse transcriptases. Thus, one of skill in the art would be unable to make and use the invention claimed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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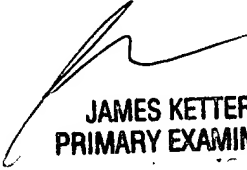
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
May 2, 2003



**JAMES KETTER  
PRIMARY EXAMINER**